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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/973,576 04/02/98 MALFROY-CAMINE B 15390-00013U

HM22/1106

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EXAMINER

SCHWADRON, R

ART UNIT	PAPER NUMBER
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1644

19

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
08/973,576

App. (s)

Malfroy-Camine

Examiner

Ron Schwadron, Ph.D.

Group Art Unit

1644



Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-22 and 24 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-5, 7-10, 12-22, 24 is/are rejected.

Claim(s) 6 and 11 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. The finality of the last Office action is withdrawn.
2. The amendment filed 1/21/2000 has been entered. The amendment filed 2/29/2000 has been entered. Regarding claim "23" in said amendment, said claim has been renumbered as claim 24 under Rule 1.126 because cancelled claim 23 was ready previously present in the instant application.
3. Claims 1-22,24 are under consideration. Claims 1,9,14,19,20 were amended in the amendment filed 1/21/2000. Claims 1,4,5,9,14,19,20 were amended in the amendment filed 2/29/2000. Claim 24 was added in said amendment

#### RESPONSE TO APPLICANTS ARGUMENTS

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 14-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,4-12,24,29-33 of copending application Serial No. 08/483,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, both sets of claims encompass methods which make the same products and compositions which contain the same ingredients. Therefore, the two sets of claims under consideration in this rejection would have been *prima facie* obvious in view of each other to one of ordinary skill in the art at the time the invention was made for the aforementioned reasons.

Applicant has indicated in the instant amendment that this issue will be addressed at a later date.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5,7-10,12-22,24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method or product using the lipid glycyldioctadecylamide, does not reasonably provide enablement for the claimed inventions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

According to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Applicant indicated that there were numerous examples in the

specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while applicant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

8. The aforementioned rejection has been discussed with BPS Schwartz.

21,22 are

9. Claims 11-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite because it is drawn to a method yet is dependent on claim 14 which is a product claim. Claims 12 and 13 are indefinite because of improper dependency. Claims 21 and 22 are indefinite in that "composition" lacks antecedent basis in claim 20.

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1600

*R.S.*

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644